201-14894A

EPA High Production Volume Program

Test Plan for

IRGANOX MD 1024

1,2-bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl)hydrazine

CAS No. 32687-78-8

Ciba Specialty Chemicals Corporation
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EXECUTIVE SUMMARY

A. Introduction

An important objective of EPA's High Production Volume (HPV) chemical challenge program is the gathering and public release of basic hazard information on those chemicals manufactured at high volumes in the United States. Ciba Specialty Chemicals has agreed to participate in this program and hereby submit for review and public comment our available data and test plan for IRGANOX MD 1024.

B. General Substance Information

Chemical Name: 1,2-bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl)hydrazine

Appearance: White to off-white powder.

Typical Commercial Purity: >98 – 100%

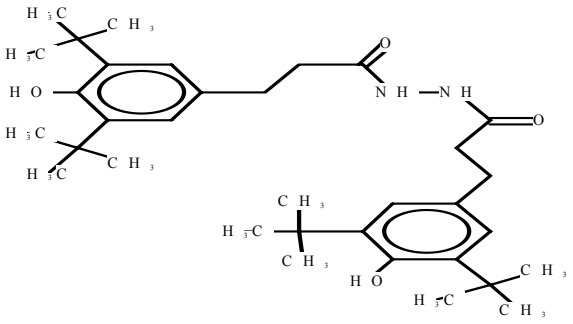
Chemical abstract Service Registry Number: CAS # 32687-78-8

Common Name / Trade Name: Irganox MD 1024

Chemical Formula: C34H52N2O4

Molecular weight: 552.8

Structure:



MolWt: 552.80 C34 H52 N2 O4

C. General Use Information

1,2-bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl)hydrazine, commercially known as Irganox MD 1024, is a primary phenolic antioxidant. Irganox MD 1024 is widely applied as a metal deactivator for telecommunications wire and cable. Irganox MD 1024 provides extraction resistance and processing stabilization.

This product has been cleared by the FDA for use in food packaging and/or applications in polymers, resins or adhesives intended for food contact applications [21 CFR (Code of Federal Regulations) § 178.2010] and [21 CFR (Code of Federal Regulations) § 175.105].

Sales of Irganox MD 1024 are to industrial users only. The polymer industry has a record of safe use of additives such as Irganox MD 1024 and worker exposures are considered minimal. Industrial Hygiene programs and Responsible Care® practices are the norm throughout the industry and it is the experience of Ciba Specialty Chemicals that its customers handle such products in a careful and conscientious manner. Ciba distributes Material Safety Data Sheets (MSDS) that present detailed hazard data and provide directions for safe handling. Ciba has established an Internal Exposure Limit for airborne exposure for Irganox MD 1024 of 10 mg/m^3 for particulate matter; this information is communicated on the MSDS. After Irganox MD 1024 is incorporated in the polymer matrix it is relatively immobile and release-exposure to humans or the environment is considered minimal.

Environmental Endpoints

Existing ecotoxicology data for this chemical indicate that there is low concern for acute toxicity to fish, aquatic plants and aquatic invertebrates. Aquatic toxicity testing was conducted with water loadings well above the solubility limits of the compound. Under environmental conditions the low solubility of the material (< 1mg/L) should preclude the occurrence of acutely toxic exposures. The compound also has very low volatility, and has a calculated n-octanol-water coeffeicient (log Pow) of > 6. Based on its physico-chemical properties, in the environment the substance is likely to bind to the soil and sediment where it is expected to be immobile and have limited bioavailability. The material is not readily biodegradable. Based on its present use environmental exposures are expected to be negligible.

Toxicology Endpoints

Available mammalian acute toxicity data indicates very low toxicity by oral, or inhalation exposure. Irganox MD 1024 is neither teratogenic nor embryotoxic and it does not impact reproductive organs, even at relatively high exposure levels. Additionally, the compound is not mutagenic or clastogenic. In a subchronic 28 day

toxicity study in the rat, there are no adverse effects up to 1000 mg/kg bw per day. In the subchronic 90 day toxicity study, there are minor effects on the weight of liver and testes in males. In females liver-derived side-effects in the plasma are observed. The NOEL is 25 mg/kg bw/day (400 ppm). All toxicological endpoints are fulfilled.

Conclusions

The available data is sufficient to meet the requirements of the HPV challenge program and no additional testing is proposed.

SUMMARY TABLE

CAS No. 32687-78-8			
PHYSICAL/CHEMICAL ELEMENTS	**DATE**	**RESULTS**	**FULFILLS REQUIREMENT**
Melting Point		227 – 232 °C	Yes
Boiling Point	2003	741.68 °C	Yes
Vapor Pressure	2003	1.04×10^{-20} mm Hg	Yes
Partition Coefficient	2003	Log Kow > 7.79 (estimated)	Yes
Water Solubility	2003	< 1 mg/L (experimental data) 2.75×10^{-4} mg/L (calculated data)	Yes
ENVIRONMENTAL FATE AND PATHWAYS ELEMENTS			
Photodegradation	2003	For reaction with hydroxyl radicals, predicted rate constant = 54.7×10^{-12} cm^3/molecule-sec Predicted half-life = 2.3 h	Yes
Stability in Water	2003	EPIWIN model estimated extremely slow hydrolysis and t1/2 is > 1 year	Waiver
Fugacity	2003	Predicted distribution using Level III fugacity model Air 0.0271 % Water 1.23 % Soil 35.6 % Sediment 63.2 % Persistence = 5.92e+003 h	Yes
Biodegradation	1984	Not biodegradable 10 mg/L: 6% in 28 days 20 mg/L: 1% in 28 days	Yes
ECOTOXICITY ELEMENTS			
Acute Toxicity to Fish	1977	LC_{50} (96 h) > 100 mg/L	Yes
Toxicity to Aquatic Plants	1993	EC_{50} (0-72 h) > 19.8 mg/L	Yes
Acute Toxicity to Aquatic Invertebrates	1990	EC_{50} (24 h) > 15 mg/L	Yes

SUMMARY TABLE (CONTINUED)

CAS No. 32687-78-8 HEALTH ELEMENTS	DATE	RESULTS	FULFILLS REQUIREMENT
Acute Toxicity	1980	Rat: LD_{50} (Oral) > 7,000 mg/kg	Yes
	1983	Chinese Hamsters: LD_{50} (Oral) > 5,000 mg/kg	
	1972	Rat: LD_{50} (Inhalation) > 110 mg/ m^3	
Genetic Toxicity • In Vitro (Ames)	1980	Ames Test – Salmonella typhimurium: No increase in mutations with or without metabolic activation (at doses of 25, 75, 225, 675, and 2025 ug/0.1 ml)	Yes
• In Vivo (Nucleus Anamoly Test)	1983	No clastogenic effect in Chinese Hamster bone marrow cells	Yes
Repeated Dose Toxicity • 4- Week dietary toxicity study in rats	1983	NOEL = 10000 ppm in females	Yes
• 90-Day dietary toxicity study in rats	1984	NOEL = 400 ppm	
Developmental and Reproductive Toxicity • 90-Day Subchronic study	1984	No significant effect on reproductive organs.	Yes
• Teratogenicity study	1983	No teratogenic effects in the rats.	